

THAT WHICH IS CLAIMED IS:

1. A stabilized HSA-free pharmaceutical composition comprising substantially monomeric interferon-beta (IFN- β) or biologically active variant thereof
5 solubilized in a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises a buffer at a concentration of about 2 mM to about 7 mM, said composition having a pH within plus or minus 0.5 units of a specified pH, where the specified pH is about 3.0 to about 5.0, said formulation having an ionic strength that is not greater than about 60 mM, and wherein said composition further
10 comprises trehalose.
2. The composition of claim 1, wherein said trehalose is present at a concentration of about 9% by weight per volume.
- 15 3. The composition of claim 1, wherein said buffer is present at a concentration of about 2 mM to about 5 mM, and said ionic strength is not greater than about 20 mM.
4. The composition of claim 1, wherein said specified pH is about 4.0 and
20 wherein said buffer is aspartic acid.
5. The composition of claim 1, wherein said composition is a liquid.
6. The composition of claim 1, wherein said IFN- β is recombinantly
25 produced.
7. The composition of claim 6, wherein said IFN- β is human IFN- β (hIFN- β) or biologically active mutein thereof.
- 30 8. The composition of claim 7, wherein said mutein is hIFN- β_{ser17} .

9. A stabilized HSA-free pharmaceutical composition comprising substantially monomeric interferon-beta (IFN- β) or biologically active variant thereof solubilized in a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises aspartic acid as a buffer, where said buffer is present at a concentration of about 1 mM to about 30 mM, said composition having a pH of about 3.5 to about 4.5, and wherein said formulation has an ionic-strength that is not greater than about 60 mM, wherein said composition further comprises trehalose.

10. The composition of claim 9, wherein said buffer is present at a concentration of about 2 mM to about 5 mM, said pH is about 4.0, and said ionic-strength is not greater than about 20 mM.

11. The composition of claim 10, wherein said composition comprises about 9% trehalose by weight per volume.

12. The composition of claim 9, wherein said IFN- β is recombinant human IFN- β (rhIFN- β) or biologically active mutein thereof.

13. The composition of claim 12, wherein said mutein is hIFN- β_{ser17} .

14. The composition of claim 9, wherein said IFN- β or biologically active variant thereof is present at a concentration of about 0.01 mg/ml to about 20.0 mg/ml.

15. A stabilized HSA-free pharmaceutical composition comprising substantially monomeric interferon-beta (IFN- β) or biologically active variant thereof solubilized in a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises aspartic acid as a buffer, where said buffer is present at a concentration of about 2 mM to about 7 mM, said composition having a pH of about 3.5 to about 4.5, and wherein said formulation has an ionic-strength that is not greater than about 60 mM, said composition further comprising trehalose.

16. The composition of claim 15, wherein said buffer is present at a concentration of about 2 mM to about 5 mM, said pH is about 4.0, and said ionic-strength is not greater than about 20 mM.

5 17. The composition of claim 16, wherein said composition comprises about 9% trehalose by weight per volume.

18. The composition of claim 15, wherein said IFN- β is recombinant human IFN- β (rhIFN- β) or biologically active mutein thereof.

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19. The composition of claim 18, wherein said mutein is hIFN- β_{ser17} .

20. A method for preparing an HSA-free pharmaceutical composition comprising substantially monomeric interferon-beta (IFN- β) or biologically active variant thereof, said method comprising preparing said composition with a low-ionic-strength formulation and trehalose, wherein said low-ionic-strength formulation is a solution that comprises aspartic acid as a buffer, where said buffer is present at a concentration of about 2 mM to about 7 mM, said composition having a pH of about 3.5 to about 4.5, and wherein said formulation has an ionic-strength that is not greater than about 60 mM, and incorporating IFN- β or biologically active variant thereof into said composition.

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21. The method of claim 20, wherein said buffer is present at a concentration of about 2 mM to about 5 mM, said pH is about 4.0, and said ionic strength is not greater than about 20 mM.

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22. The method of claim 21, wherein said composition comprises about 9% trehalose by weight per volume.

23. The method of claim 20, wherein said composition is a liquid.

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24. A pharmaceutical composition produced according to the method of claim
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